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| 10/690,791 | 10/22/2003 | Alan R. Hirsch | INS-31875(1) | 5622 |
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| EXAMINER | | | | |
| FLOOD, MICHELE C | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/690,791

Applicant(s)

HIRSCH, ALAN R.

Examiner

Michele Flood

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-9, 26, 27, 31-33 and 41-47 is/are pending in the application.
- 4a) Of the above claim(s) 6-9, 27 and 31-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 26 and 41-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/11/2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 11, 2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 26 and 41-46, and Claim 47, as amended, remain/is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues that "the results of Applicant's experimental example in the Test Study, fully supports Applicants' claims that odorant mixtures can be administered to an individual to alter their perception of the body weight of another person". However,

Applicant's arguments are not persuasive. Therefore, the rejection remains the same for the reason set forth in the previous Office action and repeated immediately below.

The claims are directed to a method of modifying perception of body weight, comprising the step of: administering to a first person for inhalation an effective amount of a composition comprising a hedonically positive mixture of a floral odorant and a spice odorant in effective amounts such that the person perceives the body weight of a second person to be about 5-10% less than actual body weight of said second person, wherein the floral odorant is selected from the group consisting of jasmine, lilac, lily of the valley, magnolia, rose, lavender, geranium, hyacinth, orange blossom, apple blossom and carnation, and the spice odorant is selected from the group consisting of cinnamon, ginger, cloves, nutmeg and oriental spice. The claims are further drawn to the method of claim 1, wherein the composition comprises a suprathreshold but non-irritant concentration of the floral odorant and the spice odorant; wherein administering the composition comprises dispensing the composition from a dispensing device; wherein administering the composition comprises applying the composition onto the first person; wherein the floral odorant is a mixture of floral odorants and the spice odorant is a mixture of spice odorants; and, wherein the body mass index of the second person is about 25 or greater; further comprising, prior to administering the composition, testing olfactory ability of the first person. The claims are further drawn to the method of Claims 42, wherein testing the olfactory ability of the first person comprises administering a forced-choice, scratch-and-sniff identification test. The claims are further drawn to the method of Claim 1, further comprising, prior to administering the

compositions, testing olfactory threshold of the first person. The claims are further drawn to the method of Claims 42, wherein testing the olfactory ability of the first person comprises administering a forced-choice, scratch-and-sniff identification test. The claims are further drawn to the method of Claim 44, wherein testing the olfactory threshold of the first person comprising administering a series of dilutions of an odorant substance in ascending order. The claims are further drawn to the method of Claim 45, wherein the odorant substance is selected from the group consisting of butyl alcohol, phenylethyl alcohol and pyridine. The claims are further drawn to the method of Claim 1, further comprising, prior to administering the composition, asking the first person to identify the mixture of the floral odorant and the spice odorant as either hedonically positive or hedonically negative.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation added to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

Nature of the Invention. The claims are directed to a method of modifying perception of body weight, comprising the step of: administering to a first person for inhalation an effective amount of a composition comprising a hedonically positive

mixture of a floral odorant and a spice odorant in effective amounts such that the person perceives the body weight of a second person to be about 5-10% less than actual body weight of said second person, wherein the floral odorant is selected from the group consisting of jasmine, lilac, lily of the valley, magnolia, rose, lavender, geranium, hyacinth, orange blossom, apple blossom and carnation, and the spice odorant is selected from the group consisting of cinnamon, ginger, cloves, nutmeg and oriental spice.

Breadth of the Claims. The claims are broad in that a composition comprising a hedonically positive mixture of a floral odorant or a mixture of floral odorants and a spice odorant or a mixture of spice odorants are administered to any and all subjects (regardless of the gender, age, sexual proclivity or sexual preference or ethnic background of the first person) is administered to a first person for inhalation such that the first person perceives the body weight of a second person to be about 5-10% less than the actual weight of the second person (irrespective of the gender, age, sexual proclivity or sexual preference or ethnic background of the second person). The complex nature of the subject matter of the invention is clearly exacerbated by the breadth of the claims.

Guidance of the Specification and Existence of Working Examples. To determine the efficacy of a mixture of a floral odorant and a spice odorant to induce a change in men's perception of body weight of a female individual, Applicant conducted a study wherein a 5'9", 245 lb., white, cosmetic saleswoman with a body mass index (BMI) of 36.2 was used as a test model (first person). One hundred ninety-nine (199)

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male models were used as observers (second person). The specification discloses that the adult male volunteers surveyed were aged 12 to 61. Ninety-three percent (n=186) were white, 2 percent (n=4) were African-American descent, 3 percent (n=6) were Hispanic descent, and 1.5 percent (n=3) were Asian descent. The three odorants used in the test study (*i.e.*, Odorant #1 was a citrus and floral odorant mixture; Odorant #2 was a mixture of sweet pea and lily of the valley odorants; and, Odorant #3 was a mixture of floral and spice odorants) were judged to be hedonically positive by a panel at the Smell & Taste Treatment and Research Foundation, Chicago, Illinois. The specification further discloses application of the three odorants over a period of three consecutive days to the model at non-irritant, suprathreshold levels and in an amount that was predetermined to be adequate for normosmics to be able to detect the applied odorant at a non-irritant, suprathreshold level. The male volunteers gave estimations of the model's body weight with and without application of the three odorants; and, then the males were queried on their detection and hedonics of each of the Odorants 1-3. Applicant discloses statistically analyzing the gathered data for significance ($p<0.05$).

In a test pilot study conducted prior to the test study, Applicant discloses applying a lavender odorant, a pumpkin pie odorant, and cinnamon odorant individually in three different sessions to a woman subject who had a BMI of 23.0 as opposed to a BMI of 36.2 of the model in the test study. Applicant disclose, "Despite the hedonically positive nature of the three odorants (*i.e.*, lavender, pumpkin pie, cinnamon), none of the three odorants provided a weight-reducing effect on the perception of a group of male

observers. The men judged the model not to weigh any less in the presence of the three odorants that were tested.”

In the results, the specification emphasizes that the pilot study and the test study only involved men’s estimation of weight rather than women’s on the basis that weight is a correlate of attractiveness in women, not men: “Weight inversely correlates with the level of attractiveness more often when men look at women than when women look at men. Also, ‘societies’ value women’s physical attractiveness more because physical attractiveness represents a more salient way of evaluating women’s [social] role fulfillment than it does for men [citation omitted]”. From the results of the pilot study, Applicant concludes that the effect of the odorant/odorant mixture can be less pronounced in instances where an individual has a low body weight and is already perceived as being at a maximal attractive or ideal weight as opposed to an individual having a BMI of 36.2 (such as the model used in the test study). While Applicant theorizes that the instantly claimed invention is more effective in altering perception of an individuals whose BMI is greater than 25.0 (the medically defined threshold for being overweight), nowhere in the specification as originally filed does Applicant provide either a showing or data therefrom to substantiate the alleged theory. The Office notes that the pilot study did not involve either a female or a male model having a BMI greater than 25. The Office further notes that the specification fails to disclose why Applicant designates the three odorants used in the pilot study as being “hedonically positive in nature”.

Of most interest, the specification discloses, "The test study demonstrated that of the three odorant mixtures tested, only the use of a floral-spice odorant mixture had a specific effect and provided a perceived reduction of weight. In the test study, among the 50 males tested with the woman model wearing the odorant mixture of floral and spice odorants (Odorant #3), there was noted a significantly reduced perception of weight ($p=0.02$) compared to the control trials. This was a reduction of perceived weight by 4.01 pounds (a 2.4% reduction) as compared to the "no odor" control group in which the averaged perceived weight by 49 males was 172.8 pounds. Among the 100 males tested, neither the citrus-floral odorant mixture (Odorant #1) nor the sweet pea and lily of the valley odorant mixture (Odorant #2) were effective in reducing perception of weight ($p=0.1$, 0.01).

In those males who perceived Odorant #3 to be hedonically positive ($n=16$), the effect of the odorant on perceived weight of the model was even more substantial at 160.8 pounds (averaged), which was 12 pounds less than the actual weight measurement ($p=0.02$). The inhalation by those test subjects of the floral-spice odorant mixture applied to the model resulted in a 7% reduction in perceived weight ($p=0.02$) compared to the no odor control subjects."

While Applicant argues that sufficient supporting disclosure, both through the working example and descriptive discussion, teach those of ordinary skill in the art how to make and use the invention as broadly as it is claimed, and show that the odorant mixtures are useful in providing the recited effect; and, while Applicant further argues that the present disclosure includes a working example that is more than adequate to

enable one of ordinary skill in this art area to carry out the invention commensurate with the scope of claims, as required under Section 112(1), without undue experimentation, given the foregoing Applicant's arguments after full consideration have been found unpersuasive for the following reasons. Firstly, Applicant has not demonstrated or specifically disclosed which floral odorant or floral odorants and which spice odorant or spice odorants can be used to provide the making of a composition comprising a hedonically positive mixture of a floral odorant(s) and a spice odorant(s) such when administered in effective amounts to a first person for inhalation that the first person would perceive the body weight of the second person to be about 5-10% less than the actual body weight of the second person. For instance, while the specification discloses examples of floral odorants (such as those recited in the Markush group of currently amended Claim 1) and spice odorants (such as those recited in the Markush group of currently amended Claim 1), nowhere in the specification does Applicant disclose, even by the example of the disclosed Odorant #3, which odorants could be used to produce a composition comprising a hedonically mixture of a floral odorant and a spice odorant to cause the claim-designated functional weight for modifying perception of body weight or what criteria or variables to consider to arrive at such a composition. The specification merely describes a hedonically positive odorant or odorant mixture as one to which an individual has a pleasant or positive reaction to its scent. In fact, the specification fails to provide any example of "a hedonically positive mixture of a floral odorant and a spice odorant" detailing the actual ingredients contained therein to provide the functional effect for modifying perception of body weight. Moreover, the Office notes that nowhere

in the specification does Applicant describe how the Smell & Taste Treatment and Research Foundation determined the positive hedonics of Odorant #3 or what was the gender, age, sexual proclivity or sexual preference or ethnic background of the panel determining the hedonics of the odorants or odorant mixtures used in either the pilot test or test study or whether any of the odorants or odorant mixtures provided a modifying perception of body weight in the panel members. Furthermore, it is noted that the odorants are not limited to naturally occurring odorants or synthetic versions of natural occurring versions of the claim-designated floral and spice odorants. Given the variety of the claim-designated floral odorants and the claim-designated spice odorants, the skilled artisan could not reasonably extrapolate those odorants which could be mixed or the amounts of the individual floral odorants and individual spice odorants which could be mixed to produce a composition comprising a hedonically positive mixture such when administered in effective amounts could to cause a modification of body weight given such limited guidance by the specification.

Applicant urges that the results of the test study demonstrate that only administration of floral-spice odorant mixture had a specific effect and provided a perceived reduction weight. However, the Office notes that inconsistencies in the data presented in the specification as originally filed contradicts Applicant's assertion that the instantly claimed method indeed works. For example, at the outset of a three-day study (conducted in consecutive days), Applicant discloses that 199 adult male volunteers were surveyed. However, Applicant reports data from only 50 men tested with the woman wearing the odorant with the mixture of floral and spice odorants. Applicant

does not account for the other 49 adult male volunteers participating in the survey at least at the outset of the test study (that is, whether data was obtained or not obtained or deemed unsuitable for various unknown reasons), assuming that the testing of Odorants #1 and #2 were equally divided among 100 adult male volunteers. For instance, Applicant readily discloses that among 100 males tested with either the citrus-floral mixtures (Odorant #1) or the sweet pea and lily of the valley odorant mixture (Odorant #2) did not result in reducing perception of weight. Since it is unclear from the specification as to what data or observations were gathered from the unmentioned remaining male volunteers, it is uncertain as to whether the statistical analysis provided by Applicant is sound. Regardless of whether the unmentioned 49 male volunteers participated in the test study in its entirety or whether data or observations were made and was intentionally omitted or unintentionally omitted, the statistical analysis presented in the instant disclosure still warrants question because of the following:

"In the test study, among the 50 males tested with the woman model wearing the odorant mixture of floral and spice odorants (Odorant #3), there was noted a significantly reduced perception of weight ($p=0.02$) compared to the control trials. This was a reduction of perceived weight by 4.01 pounds (a 2.4% reduction) as compared to the "no odor" control group in which the averaged perceived weight by 49 males was 172.8 pounds. [text omitted] In those males who perceived Odorant #3 to be hedonically positive ($n=16$), the effect of the odorant on perceived weight of the model was even more substantial at 160.8 pounds (averaged), which was 12 pounds less than the actual weight measurement ($p=0.02$). The inhalation by those test subjects of the floral-spice odorant mixture applied to the model resulted in a 7% reduction in perceived weight ($p=0.02$) compared to the no odor control subjects."

The Office notes that the woman model used in the test study of the three odorant/odorant mixtures weighed 245 lbs. Nonetheless, among the 50 males tested with the woman model wearing Odorant #3, the males tested perceived her weight to be

only 4.1 pounds less as compared to the "no odor" control group. In other words, the males tested with the woman wearing Odorant #3 perceived the model's body weight to be 168.8 pounds, whereas the averaged perceived weight of the "no odor" male control group perceived the model's weight to be 172.8 pounds, and whereas those males who perceived Odorant #3 to be hedonically positive (n=16) perceived weight of the model was 160.8 pounds. Given that no data was provided by Applicant to demonstrate what was the tested males perception of the body weight of the woman model wearing either Odorant #1 or Odorant #2, it is unclear as to whether there was indeed a significant difference achieved among the three tested odorants because the data presented in the specification fails to explain why the tested Odorant #3 group estimated the weight of a woman weighing 245 pounds as being only 4.1 pounds less than the "no odor" control group. Moreover, it is unclear from Applicant's disclosure whether the pilot study included the same male volunteers used in the test study. The Office notes that Applicant emphasizes that the males in the pilot study did not underestimate the body weight of the woman model having a BMI of less than 25, whereas the males in the test pilot study radically underestimated the weight of the model having a BMI of 36.2. In other words, it is unclear from Applicant's disclosure what was the ability of the men tested with the three odorant/odorant mixtures to properly estimate the weight of an overweight woman or whether other factors other than the influence of the floral-spice odorant mixture played a role in the men's gross underestimation of the apparently obese woman, given that the men had observed the same female model having the

same approximate weight over a three consecutive day period of olfactory testing and were questioned as to how much the woman model weighed.

Predictability and State of the Art. As it stands, while the art recognizes and has demonstrated that odorants have an effect on perceived quality of inanimate objects, impressions of others, and perception of size or external space by humans, as well as psychological, social and sexual effects on human beings, there is no known method of modifying perception of body weight comprising administering effective amounts of a composition comprising a hedonically positive mixture of a floral odorant and a spice odorant such when inhaled by a first person the first person perceives the body weight of a second person to be 5-10% less than the actual weight of the second person. It should be noted that Applicant's premise for inducing a perception of weight reduction in person is predicated on the idea that society, as a whole, perceives a thinner body image as being more attractive than overweight subjects. This premise is specifically directed to the idea that men deem thinner women to be more attractive than obese women and that women generally perceive their social attractiveness or self-image in terms of how others perceive her weight. Given the foregoing, Applicant further urges that women understanding that those believing that she is overweight will try to attempt to project the visual image of thinness. While Applicant's premise may apply to some sectors of the population, this is not true in all societies or ethnic backgrounds. For example, Miller et al. (U) teaches, "Some research suggests that, among African-Americans, the ideal body size is larger than amount European Americans and that size is less salient in judging attractiveness." (See page 311, second paragraph). Miller

further teaches that while less research has been conducted among the Hispanic population, Guatemalan college women felt better about their bodies and were less concerned about their weight than their counterpart European American white college females, despite the fact that appearance was equally important to both groups. (See page 311, third paragraph). In a study comparing the affective and cognitive components of body image related to physical appearance, weight and health among three racial/ethnic groups, Miller reports that a pattern of racial/ethnic and gender differences exist between men and women of African American, European American and Latino/a American racial/ethnic groups. Applicant's disclosure fails to consider these differences among men and women of different racial/ethnic backgrounds and how these differences would affect the claim-designated method for modifying perception of body weight in those men and women having a positive self-image of body weight considered by European Americans as less than attractive. Most important nowhere in the specification does Applicant indicate whether the males tested were queried as to what was the ideal weight of attractive women. Even more important, nowhere in the specification did Applicant disclose what was the self-body image of the woman weighing 245 pounds before the testing or whether the odorant/odorant mixtures affected a sense of well-being or a perceived weight-reducing effect in the woman such that she had a better feeling about herself. Despite Applicant's apparent omission that the claimed method would not be operable is modifying a woman's perception of body weight in other subjects, the claims broadly read on a method of

modifying weight perception in all sectors of the population. See

<http://pherolibrary.com/forum/showthread.php?t=6442>. (V).

Amount of Experimentation Necessary. The quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not rely on the limited guidance of the specification, the prior art to teach how to make and/or use the instantly claimed method for modifying perception of body weight comprising administration of an effective amount of hedonically positive mixture of the claim-designated floral odorant(s) and the claim-designated spice odorant(s).

In view of the breadth of the claims and the lack of guidance provided by the specification and limited number of working examples, as well as the unpredictability of the art, it would take undue experimentation without a reasonable expectation of success for the skilled artisan to make and/or use the instantly claimed method.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
April 28, 2008

/Michele Flood/
Primary Examiner, Art Unit 1655